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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,184	11/25/2003	Jeffrey O. Phillips	03207556	7922
26565 7590 06/14/2007 MAYER, BROWN, ROWE & MAW LLP 71 S. WACKER CHICAGO, IL 60606			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 06/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/722,184

Applicant(s)

PHILLIPS, JEFFREY O.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 151-153, 156-161, 167-170 and 174-210 is/are pending in the application.
- 4a) Of the above claim(s) 171-173, 211-272 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 151-153, 156-161, 167-170 and 174-210 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated April 4, 2007 have been entered and considered carefully.

Claims 1-150, 154-155, 162-166 have been canceled. Claims 171-173, 211-272 stayed withdrawn from consideration. Claims 151-153, 156-161, 167-170, 174-210 are pending.

2. Claims 151-152 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claims with the specific 5-100 mg omeprazole and buffering agent about 10-70 mEq lacks antecedent basis and description in the specification. Please note that the particularity of such inventive concept must find explicit antecedent basis. Mixing and matching of variation in dosage and quantities of ingredients are considered new matter.

Removal of new matter is required. In re Russmussen 210 USPQ 325.

3. The rejection of claims 151-153, 156-157, 158-161, 167-170, 174-210 under 35 USC first paragraph is maintained for reason of record.

Applicants provided mere argument without factual evidence that all the ranges is able to achieve a 0.1 µg/ml within 30 minutes as delineated in the previous office action. Please note a result from administering the composition in fasting subject would not be supportive of the claims which does not require any limitation of the subject.

4. The rejection of claims 151-153, 156-157, 158-161, 167-170, 174-210 under 35 USC 102(b) is maintained for reason of record.

Please note that after removing of the new matter and the claims are placed to the previous version, the rejection is still applicable. In addition, the Carrol, McCulloch, Depue or

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JP '088 disclosed anticipatory composition. Absence of factual evidence, there is no support that why the same serum concentration would not be achieved.

5. The rejection of claims 151-153, 156-157, 158-161, 167-170, 174-210 under 35 USC 103(a) is maintained for reason of record.

Please note that after removing of new matter and the claims are placed to the previous version, the rejection still is applicable.

Even with the new dosage limitation, absent of factual evidence, there is no support that the current dosage would give the serum concentration only since prior art of record by Horowitz showed that the prior art composition by Carrol, McCullogh, Depue or JP '088 would give the required plasma concentration in 30 min. Please note that an acid-base combination wherein one is a weak acid or base would constituted a buffer with or without calling it a buffer.

6. The rejection of claims 151-153, 156-157, 158-161, 167-170, 174-210 under the judicially created doctrine of obviousness type double patenting over US 6,699,885; 6,645,988; 6,489,346 or 5,840,737 is maintained for reason of record.

No acceptable terminal disclaimer has been filed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

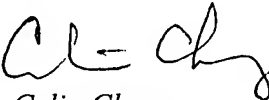
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jun. 7, 2007


Celia Chang
Primary Examiner
Art Unit 1625